202.942.5000 202.942.5999 Fax

555 Twelfth Street, NW Washington, DC 20004-1206

September 3, 2004

Mail Stop Amendment

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Re:

U.S. Patent Application No. 10/016,969

Filed:

December 14, 2001

Title:

Peptide YY and Peptide YY Agonists for

**Treatment of Metabolic Disorders** 

Applicants:

Richard A. PITTNER et al.

Atty. Docket: 18528.010 / 0401-UTL-0

Sir:

The following documents are forwarded herewith for appropriate action by the U.S. Patent and Trademark Office (PTO):

- 1. a Supplemental Information Disclosure Statement;
- 2. a PTO-1449 form (3 pages) with 20 accompanying references; and
- 3. a return postcard.

Please stamp the attached postcard with the filing date of these documents and return it to our courier.

Applicants request that the fee of \$180.00 be charged to Deposit Account No. 50-2387 referencing docket number 18528.010:

In the event that extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned. Applicants do not believe any additional fees are due in conjunction with this filing. However, if any additional fees are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Arnold & Porter LLP Deposit Account No. 50-2387, referencing matter number 18528.010. A duplicate copy of this letter is enclosed.

Respectfully submitted,

David R. Marsh (Reg. No. 41,408) Milan M. Vinnola (Reg. No. 45,979)

Attachments



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Richard A. PITTNER et al. Group Art Unit: 1646

Appln. No.: 10/016,969 Examiner: R. Li

Filed: December 14, 2001 Atty. Docket: 18528.010 / 0401-UTL-0

For: Peptide YY and Peptide YY Agonists Confirmation No.: 7314

for Treatment of Metabolic

**Disorders** 

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313

Dear Sir:

The attention of the Examiner is invited to the documents listed on the attached Form PTO-1449. Copies of the listed documents are submitted herewith. Applicants make no admission that the cited references constitute prior art against the present application.

It is respectfully requested that the information above be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

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<sup>&</sup>lt;sup>1</sup> The references submitted herewith include references that were discussed in the Response filed July 6, 2004.

## **CERTIFICATION AND/OR FEE**

Because this Information Disclosure Statement is being submitted after issuance of the first action on the merits of the above-captioned application, a fee of \$180.00 is due pursuant to 37 C.F.R. § 1.17(p). Applicants request that this fee be charged to Deposit Account No. 50-2387 referencing docket number 18528.010.

Respectfully submitted,

David R. Marsh (Reg. No. 41,408) Milan M. Vinnola (Reg. No. 45,979)

Date: September 3, 2004

ARNOLD & PORTER LLP 555 Twelfth Street, N.W. Washington, D.C. 20004-1206 (202) 942-5000 telephone (202) 942-5999 facsimile



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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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1	Substitute for form 1	449 A/PTO				
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SUPPLEMENTAL FORM PTO-1449				Application Number	10/016,969	
•	CRWI PTO-14	47		Filing Date	Dec 14, 2001	
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				Examiner Name	Ruixiang Li	
Sheet	1	of	3	Attorney Docket Number	0401-UTL-0	

U.S. PATENT DOCUMENTS						
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Examiner Initials *	Cite No. <sup>1</sup>	Number Kind Code <sup>2</sup> (if known)	Publication Date MMDDYYYY	Name of Patentee or Applicant of Cited Document	Relevant Passages or Relevant Figures Appear	

	FOREIGN PATENT DOCUMENTS								
Examiner	Cite	Foreign Patent Document	Publication Date	Name of Patentee or Applicant	Pages, Columns, Lines,				
Initials *	No.1	Country Code <sup>3</sup> Number <sup>4</sup> -Kind Code <sup>3</sup> (if known)	MM-DD-YYYY	of Cited Document	Where Relevant Passages or Relevant Figures Appear	T <sup>4</sup>			

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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw tine through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number(optional). <sup>3</sup>See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>3</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.



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				Application Number	10/016,969	
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				Examiner Name	Ruixiang Li	
Sheet	2	of	3	Attorney Docket Number	0401-UTL-0	

	r	OTHER PRIOR ART -NON PATENT LITERATURE DOCUMENTS	T
Examiner Initials •	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>3</sup>
		Adrian TE, et al., "Lack of effect of pancreatic polypeptide in the rate of gastric emptying and gut hormone release during breakfast" Digestion. 1981 21:214-8.	
<u> </u>		Beltowski, J., et al., "What we know 10 years since its discovery?" Pol J Pharmaco. 2004;56:5-27.	
		Camilleri, M, et al., "Effects of vasoactive intestinal peptide and pancreatic polypeptide in rabbit intestine" Gut. 1981 22:14-8.	
		Cox, HM, et al., "The effecto neuropeptide Y and peptide YY on electrogenic ion transport in rate intestinal epithelia" J Physio. 1988 Apr;398:65-80.	
		Ebert, R., "Control of gastric empyting by regulatory peptides" Z Gastroenterol Verh. 1988 23:165-70.	
		Gustavsson S, et al., "Effects of vasoactive intestinal peptide and pancreatic polypeptide on small bowel propulsion in the rat" Gastroenterol. 1997 12:993-7.	
		Harding, RK, et al., "Identification and characterization of the emetic effects of peptide YY" Peptides 1989 10:24-4.	
-		Kruger, DF, et al., "Clinical implication of amylin and amylin deficiency" Diabetes Educator 1999;25:389-398.	
		Martin, JR, "The Y1 receptor subtype mediates the cardiovascular changes evoked by NPY administered into the posterior hypothalamic nucleus of conscious rat" Brain Res. 2004 1002:11-20.	
		Nightingale, JM, et al., "Gastrointestinal hormones in short bowel syndrome. Peptide YY may be the 'colonic brake' in gastric emptying" Gut. 1996 Aug;39(2):267-72.	
···		Okumura, T, et at., "Intracisternal injection of pancreatic polypeptide stimulates gastric emptying in rates" Neurosci Lett. 1994 178(1):167-70.	
		Pheng, et al., "Agonist- and antagonis-induced sequestration/internalization of neuropeptide Y Y <sub>1</sub> receptors in HEK293 cells" British J of Pharma 2003 139:695-704	
		Pironi, L, et al., "Fat-reduced ileal brake in humans: a dose-dependent phenomenon correlated to the plasma levels of peptide YY" Gastroenterology. 1993 105:733-9.	
		Sainsbury, A, et al., "Y4 receptor knockout rescues fertility in ob/ob mice" Genes Dev. 2002 16:1077-88.	
		Servin, AL, et al., "Peptide-YY and neuropeptide-Y inhibit vasoactive intestinal peptide- stimulated adenosine 3',5'-monophosphate production in rat small intestine: structural requirements of peptides for interacting with peptide-YY-preferring receptors"	

Examiner	Date	
Signature	Considered	

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SUPPLEMENTAL FORM PTO 1440				Application Number	10/016,969	
FORM PTO-1449				Filing Date	Dec 14, 2001	
(use as many sheets as necessary)				First Named Inventor	Pittner, R.A.	
				Art Unit	1646	
				Examiner Name	Ruixiang Li	
Sheet	3	of	3	Attorney Docket Number	0401-UTL-0	

Endocrinology. 1989 Feb;124(2):692-700.
Taylor, IL, et al., "Effects of pancreatic polypeptide, caerulein, and bombesin on satiety in obese mice" Am J Physiol. 1985 248:G277-80.
 Taylor, IL, "Role of peptide YY in the endocrine control of digestion" J Dairy Sci. 1993 76:2094-101.
Wager-Page, SA, et al., "Peripheral modulation of duodenal and colonic motility and arterial pressure by neuropeptide Y, neuropeptide Y fragment 13-36, peptide YY, and pancreatic polypeptide in rates: cholinergic mechanisms" Can J Physiol Pharmacol. 1993 71:768-75.
Wimalawansa, "Amylin, Calcitonin Gene-related Peptide, Calcitonin, and Adrenomedullin: A Peptide Superfamily, Neurobiology, (2&3):167-239 (1997)
Young, AA, et al., "Dose-responses for the slowing of gastric emptying in a rodent model by glucagon-like peptide (7-36) NH2, amylin, cholecystokinin, and other possible regulators of nutrient uptake" Metabolism. 1996 45:1-3.

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